

Application No. 09/710,394  
Page 10

Amendment  
Attorney Docket No. S63.2-11048

**Remarks**

New claims 22-33 have been added. Support for these claims comes from page 7, lines 6-10 and from the claims as originally filed.

**Rejections**

**35 U.S.C. §112**

Claims 1-21 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that the specification does not describe the chemical nature of the urethane polymers employed in making the catheter balloon material claimed, and that the mere recitation of trademarks/tradenames, without a definite description of the polymers referred to by those names, is not a sufficient disclosure (see MPEP 608.01(v)).

The paragraph on page 10 of the specification has been amended to incorporate the chemical description of the polymers as well as the trademarks/tradenames. Applicants respectfully request withdrawal of the rejection of claims 1-21 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

**35 U.S.C. §103(a)**

Claims 1-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ward (US 5,815,705). The Office action asserts that Ward teaches the production of catheters (col. 1, lines 24-25) from block copolymers produced so that it has tailored glass transition temperatures ("GTT") (col. 8, lines 34-62). The block copolymer may be from urethane blocks (claim 3 of the patent at col. 14, lines 53-59).

Applicants traverse the rejection.

**Ward et al., US 5,814,705**

Ward et al. describe a composition that softens at a predetermined temperature, preferably between about 20° C and 90° C, and more preferably between about 20° C and about 62° C, comprising at least *one block copolymer having at least two thermal transition temperatures*. The composition is characterized by at least two

Application No. 09/710,394  
Page 11

Amendment  
Attorney Docket No. S63.2-11048

thermal transition temperatures, one of which is a predetermined lower transition temperature, preferably between about 20° C to 90° C, and more preferably between about 20° C to about 62° C, and one of which is an upper transition temperature. (Abstract, col. 2, lines 12-15 and col. 8, lines 33-37).

Claim 1 of the present invention, in contrast, is directed to catheter balloon material formed from a *blend* of at least one first polyurethane having a first glass transition temperature in the range of -37 to 10 degrees C and at least one second polyurethane having a glass transition temperature in the range of 20 to 31 degrees C.

Independent claim 9 is directed to a catheter balloon material formed from a blend of polymeric components in which the first polymer has a glass transition temperature in the range of 0 to 10 degrees C and in which the second polymer has a glass transition temperature in the range of 65 to 100 degrees C.

Independent claim 13 is directed to an embodiment in which a catheter balloon material is formed from a blend of polymeric components in which a first polymer has a different Shore D hardness than the second polymer.

Thus, the present invention in each embodiment is directed to a blend of at least two polymers, each of which has a glass transition temperature different from the other or each of which has a Shore D hardness associated with it, as opposed to Ward et al., which is directed to at least one polymer having two different transition temperatures.

The single block copolymer described in Ward et al. having two glass transition temperatures is not obtained by blending two polymers as described in the present invention, contrary to what is asserted on page 4, in the 5<sup>th</sup> paragraph of the Office Action.

Ward et al. in fact is mute as to Shore D hardness values.

Consequently, Applicants submit that claims 1-15 are not obvious over Ward et al. and Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §103(a).

Claims 1-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lee (US 6,284,856). The Office Action asserts that Lee teaches catheters (col. 3, line 64) made from compositions containing two copolymers, one with a

Application No. 09/710,394  
Page 12

Amendment  
Attorney Docket No. S63.2-11048

GTT of -50 to 10 degrees C and a second one with a GTT of 12 to 65 degrees C (col. 8, lines 5-13) and that the two copolymers are derived from urethane oligomers (col. 3, lines 23-24 and col. 7, lines 9-11).

Applicants traverse the rejection.

*Lee, US 6,284,856*

Lee describes acrylic-based copolymers for *coating* rubber articles to provide improved mold release characteristics, improved donning characteristics, and improved tactile feel. The copolymer is formed by the polymerization of a low surface energy monomer, an alkyl acrylate, a hard monomer and a urethane oligomer. The copolymers are preferably formed by a sequential polymerization process. See the Abstract, and col. 2, lines 1-3.

The Office Action asserts that Lee teaches catheters made from compositions containing two copolymers, one with a GTT of -50 to 10 degrees C and a second one with a GTT of 12 to 65 degrees C, formed from urethane oligomers, and that oligomers are known in the polymer art to be polymers, so that the urethane oligomers are polyurethanes.

Applicants disagree. Lee teaches *coatings* formed from the acrylic-based copolymers described therein which can be used to coat or to be absorbed on the surface of rubber articles. See the Summary of the Invention, col. 2, lines 50-62. Lee makes no suggestion to employ the acrylic-based copolymer to *form* a catheter, nor in fact makes any suggestion to employ the compositions to form articles at all. Further, the acrylic-based copolymer is formed from a low surface energy monomer, an alkyl acrylate, a hard monomer and a urethane oligomer, the reaction of which does not form a polyurethane.

The Office Action also asserts that oligomers are known in the polymer art to be polymers, so that the urethane oligomers are polyurethanes. It is true that by definition an oligomer is a polymer. However, it is a polymer which consists of only a few monomer units such as a dimer, trimer or tetramer. *Hawley's Condensed Chemical Dictionary*, Twelfth Edition, Lewis, Richard J. Sr., Van Nostrand Reinhold Co., New York, 1993, pg. 853. A polymer, in contrast, is defined in the same dictionary as a

Application No. 09/710,394  
Page 13

Amendment  
Attorney Docket No. S63.2-11048

macromolecule formed by the chemical union of five or more identical combining units called monomers. *Hawley's Condensed Chemical Dictionary* at 936. Copies of these pages have been included.

Oligomers are typically employed as reactants in the formation of larger polymer molecules. Such is the case in Lee. The urethane oligomers are actually employed as reactants in the formation of the acrylic-based copolymers described therein, the resultant copolymer of which would not be characterized as a polyurethane. Lee does not suggest employing the urethane oligomers for blending as in the present application, but rather for reacting to form a copolymer.

The Office Action directs us to col. 7, lines 9-12, suggesting that the motivation to employ the urethane oligomers of Lee in its copolymers and blends, comes from the fact that Lee suggests the use of urethane oligomers to produce a matte finish which prevents blocking. Again, these urethane oligomers are reacted with other monomers, including an acrylate, to form a copolymer which is not a polyurethane. Lee then suggests using the copolymer to *coat* an article to produce a matte or low gloss finish to the *coated* article (col. 7, lines 9-11).

Thus, even if the copolymer of Lee were the same as those described in the present invention, which they are not, Lee makes no suggestion that such copolymers are useful as catheter balloon materials.

In summary, the copolymers described by Lee are not polyurethanes as described and claimed in the present specification, the urethane oligomers are employed as reactants to form the copolymers not for blending, and the copolymers are used as coatings, not as catheter balloon materials. Applicants submit that Lee has none of the elements of the present invention. Consequently, none of the teachings of Lee lead to the catheter balloon material formed from a blend of polyurethanes described and claimed in the present invention.

Applicants respectfully request withdrawal of the rejection of claims 1-21 under 35 U.S.C. §103(a) as being obvious over Lee.

Application No. 09/710,394  
Page 14

Amendment  
Attorney Docket No. S63.2-11048

**CONCLUSION**

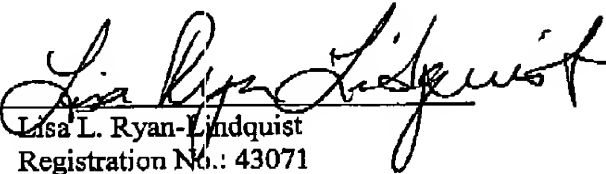
Claims 16-21 were not addressed in the Office Action.

Respectfully submitted,

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